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| EXAMINER |
|---|
| BERHANU, ETSUB D |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/604,851 | BUCHERT, JANUSZ MICHAL | |
| | Examiner | Art Unit | |
| | Etsub D. Berhanu | 3768 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 August 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/19/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Claim Objections*

1. Claims 5, 11-13, 15 and 16 are objected to because of the following informalities: the term - - measurements - - should be inserted after the term "temperature" in line 2 of claim 5; the term - - a - - should be inserted between the terms "incorporating" and "body" in line 2 of claim 11; the comma after the term "an" in line 8 of claim 16 should be deleted. Claims 11-13 and 15 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim and should refer to other claims in the alternative only. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits. Appropriate correction is required.

### *Claim Rejections - 35 USC § 112*

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 9, 12, 13, 16 and 17-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 9, 12 and 13 fail to provide any further structural limitation and are therefore indefinite. The phrases "said speculum optionally comprising a body temperature sensors by conduction" in lines 27-28 of claim 16 and lines 22-23 of claim 17 are unclear and therefore render the claims indefinite. Claims 16 and 17 recite the limitation "said sensors" in lines 32 of claim 16 and line 27 of claim 17. There is insufficient antecedent basis for this limitation in the claims.

### *Claim Rejections - 35 USC § 102*

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 2, 14 and 15 are rejected under 35 U.S.C. 102(e) as being anticipated by Malchoff et al. (cited by Applicant).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Malchoff et al. discloses a method of continuously determining a human body tissue analyte concentration by non-invasive measurement of emission spectral lines characteristic to a body tissue analyte in an infrared spectral region emitted naturally by a human body as heat, the method comprising: measuring a spectral intensity of emission lines having a wavelength dependence of tissue constituents, detecting the emission spectral lines at a predetermined emission wavelength, analyzing the emission spectral lines in the infrared spectral region, measuring ambient temperature, measuring ambient humidity, measuring body temperature by means of heat conduction, measuring body temperature in a non-contact manner by means of radiation and correlating the spectral intensity of emission spectral lines, ambient temperature, ambient humidity, the body temperature measured by means of heat conduction and the body temperature measured by means of heat radiation, with a blood glucose analyte level (page 2270, col. 3, line 4 – page 2271, col. 2, line 24).

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buchert'956 (cited by Applicant) further in view of Schulze et al.'852 (USPN 6,556,852) further in view of Braig et al.'672 (cited by Applicant).

Buchert'956 discloses an instrument for determining a glucose concentration by non-invasive measurement of emission spectral lines in an infrared spectral region emitted naturally by a tympanic membrane as heat (see ABSTRACT), the instrument comprising: an ear plug assembly comprising an infrared radiation detecting system comprising an optical infrared filter set and a detector sensitive in an infrared region of human body heat radiation and an optical waveguide or mirror or lens, a body temperature measurements sensor, connection means between the ear plug assembly and the sensor, electronics, a microcomputer and a display so that the system is capable of forming, calculating and displaying a resulting electrical signal from the detector and sensors to show a numerical value of the glucose concentration, wherein the detecting system incorporating a body temperature sensor is adapted to be in thermal conductive contact with a human body and the ear plug assembly consists of a plastic cover made of material transparent to radiation in an infrared spectral region (col. 9, lines 35-64). Buchert'956 further discloses the instrument comprising an optical infrared filter set consisting of windows and a negative correlating filter or narrow band filters (see ABSTRACT and col. 9, line 65 – col. 10, line 34). Buchert'956 also discloses a detector system sensitive in an infrared region of human body heat radiation consisting of at least two sensing areas electronically connected so that their outputs are subtracted (col. 8, line 60 – col. 9, line 9).

Buchert'956 further discloses a method of continuously determining a blood glucose concentration by non-invasive measurement of emission spectral lines in an infrared spectral region emitted naturally by a human body as heat, the method comprising: measuring a spectral intensity of said

emission lines having a wavelength dependence on blood glucose, detecting the emission spectral lines at a predetermined emission wavelength, analyzing the emission spectral lines in said infrared spectral region, measuring body temperature and correlating said spectral intensity of emission spectral lines, a measured ambient temperature and measured body temperature with a blood glucose concentration (see ABSTRACT and col. 8, line 55 – col. 10, line 28).

It is noted that while Buchert'956 does not directly disclose measuring ambient temperature or a means for measuring ambient temperature or body temperature, that it does disclose that a measure of ambient temperature is required (col. 9, lines 58-64) and indicates that the method requires an additional sensor for temperature measurements of the body (col. 10, lines 41-43). In being able to "compensate for the ambient temperature changes", the instrument and method of Buchert'956 inherently comprise means for measuring an ambient temperature sensor and further a step of measuring ambient temperature. Schulze et al.'852 teaches adding a reference temperature sensor to a tympanic thermometer measuring core body temperature in a non-contact manner by means of radiation in order to be able to measure ambient temperature and compensate a physiological measurement for ambient temperature. It would have been within the skill of the art to incorporate the ambient temperature sensor and non-contact tympanic thermometer of Schulze et al.'852 into the ear assembly sensor of Buchert'956 since Buchert'956 requires an ambient temperature to be measured, but fails to disclose the details of a means for acquiring an ambient temperature measurement, and Schulze et al.'852 provides one such means. Further, the ambient temperature sensor and tympanic thermometer of Schulze et al.'852 would allow the measurement obtained by the instrument to be compensated for ambient temperature, thus resulting in a more accurate blood glucose concentration.

In regards to the "additional sensor for temperature measurements of the body" disclosed in col. 10, lines 41-43, Braig et al.'672 teaches the use of a body temperature sensing means by heat conduction in order to compensate a physiological measurement for temperature dependent effects (col. 12, lines 44 –

56). It would have been within the skill of the art to implement the temperature sensing means of Braig et al.'672 with the instrument of Buchert'956 since Buchert'956 requires the use of an additional sensor for temperature measurements of the body, but fails to disclose the details of a means for acquiring an additional body temperature measurement, and Braig et al.'672 provides one such means. Further, the body temperature sensing means of Braig et al.'672 would allow the measurement obtained by the instrument to be compensated for temperature dependent effects, thus resulting in a more accurate blood glucose concentration.

Regarding the limitations in the claims referring to an optional ambient humidity measurement or sensor, no patentable weight was given to these limitations in the claims because the terms "optionally" and "optional" imply that these limitations are not required for the instrument and method.

***Conclusion***

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. As disclosed in the Specification, the reference of Buchert'966 (cited by Applicant) discloses all of the elements of the current invention except for directly disclosing an ambient temperature sensor and a body temperature sensor integrated into the ear assembly sensor. Cooper et al.'884 (USPN 6,309,884) teaches using ambient temperature sensors and ambient humidity sensors to acquire ambient temperature and humidity measurements to compensate a noninvasive blood glucose measurement. Hatch et al.'874 (USPN 6,918,874) also discloses using an ambient humidity measurement to compensate a measurement of an analyte in a biological fluid.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Etsub D. Berhanu whose telephone number is 571.272.6563. The examiner can normally be reached on Monday - Friday (Every other Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on (571)272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

EDB

ERIC F. WINAKUR
PRIMARY EXAMINER